## Exhibit I

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times since Dr. Grassi's pioneering work in the original ones.

And these guidelines recognize, as the medical community do,
that there are complications with these devices, all devices,
not just Bard's.

And these guidelines show, if you will look at the third line, that filter fracture, the complication that Ms.

Jones unfortunately sustained, occur in 2 to 10 percent of patients. Why the doctors keep implanting these in patients when they know, and the medical community knows they can fracture that often, the evidence will show, you because they decide, day in and day out, that the life-threatening nature of a pulmonary embolism is so great that the lifesaving benefit of the device outweighs its risks.

Now, these IVC filters are not just somebody snaps their fingers at Bard Peripheral in Tempe and starts selling them. It is a long process to get clearance from the FDA to sell these. Bard must demonstrate that a device that is developing and wants to sell is substantially equivalent to an earlier already cleared device.

Now, the FDA has a wealth of experience with inferior vena cava filters. Two decades ago in 1996 the FDA carefully weighed the risks and benefits of all these devices, not looking at Bard filters but all filters. And the FDA recognized in assessing these devices that all filters present the risk of complications and recognized that many of these

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